Comparison of North American Symptomatic Carotid Endarterectomy Trial and population-based outcomes for carotid endarterectomy

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Purpose: **The North American Symptomatic Carotid Endarterectomy Trial (NASCET) advocated the use of carotid endarterectomy (CEA) for transient ischemic attacks (TIAs), nondisabling strokes, and ipsilateral high-grade stenosis in highly selected patients. Whether similar results are achieved when CEA is applied to an entire geographically defined population is unknown but important if the NASCET recommendations are to be applied broadly to all community patients.**

Methods: **To determine the survival rate to ipsilateral stroke after CEA for all symptomatic patients in a defined population, we reviewed the medical records of all patients residing in Olmsted County, Minn. (approximately 100,000), who underwent a CEA for TIA or nondisabling stroke between 1970 and 1995. Their outcomes were compared with the NASCET results.**

Results: **In the community of Olmsted County, 297 patients (108 women and 189 men) underwent 322 CEAs during the study period. TIAs or nondisabling stroke was the indication in 254 patients (86%), whereas the remaining 14% had asymptomatic stenosis. After CEA for symptomatic lesions, survival rate free of ipsilateral stroke was 97% at 2 years, 93% at 5 years, and 92% at 10 years. These results are similar to the NASCET survival rates free of ipsilateral stroke at 2 years (91%). However, the 30-day postoperative stroke rate for patients older than 80 years was significantly higher than that for patients younger than 80 years.**

Conclusions: **When the NASCET results are compared with a population-based experience in which all symptomatic patients undergoing CEA were analyzed, the early outcomes were similar. Our population-based data also document the remarkably durable long-term results of CEA in preventing stroke and present another benchmark for carotid stent angioplasty. (J Vasc Surg 1998;27:845-51.)**

The results of prospective, randomized clinical trials have been used to determine that carotid endarterectomy is preferable to medical management for patients with symptomatic high-grade carotid stenosis.[1-3] One of the most widely quoted confirmations of this practice guideline remains the North American Symptomatic Carotid Endarterectomy Trial (NASCET).[1] As a multicenter study, NASCET included a subset of all symptomatic patients who presented to a variety of participating centers. NASCET also included a subset of surgeons who had a high level of surgical expertise.

These inclusion criteria for patients and surgeons may have introduced selection bias into the applicability of the NASCET recommendations to a general community population. For example, NASCET excluded patients older than 80 years, yet this elderly subset is becoming more prevalent in practice. In addition, some community and state reports of

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carotid endarterectomy reveal that the average number of such operations per year per surgeon is remarkably low and the outcomes vary notably.[4]

To determine whether the conclusions of NASCET are applicable to general community practice, we compared the characteristics and outcomes of patient enrolled in NASCET with those of all residents of a geographically defined community who underwent elective carotid endarterectomy for transient ischemic attacks (TIAs) or nondisabling stroke between l970 and 1995. Because the initial report of NASCET had the relatively short follow-up period of only 18 months, we also used our 25-year database to address the critical issue of durability of the initial benefit of carotid endarterectomy compared with that of medical therapy.

METHODS

Source of data. Olmsted County, Minn., provides a unique database for large-scale population-based investigations of cerebrovascular disease.[5] Virtually all residents of the community receive their medical care at the Mayo Clinic, Olmsted Medical Group, or Olmsted Community Hospital. Carotid operations are performed exclusively at the Mayo Clinic. A medical record diagnostic indexing system provides access to the details of all patient encounters, both inpatient and outpatient, and has supported numerous studies of cardiovascular and other diseases.[5] Because all patients who underwent carotid operation did so at the Mayo Clinic, their early and late postoperative care also was conducted exclusively at the Mayo Clinic. This study was reviewed and approved by the Mayo Institutional Review Board.

Carotid endarterectomy cohort. All 297 Olmsted County residents who underwent an initial elective carotid endarterectomy between l970 and l995, inclusive, were identified. Preoperative indication for operation was classified as either symptomatic (TIAs or nondisabling stroke) or asymptomatic high-grade stenosis. Only patients with atherosclerotic carotid disease were included, and any patients who underwent an emergency carotid endarterectomy was excluded.

Data collection. Data abstracted from the medical records of the subset of patients with cerebrovascular symptoms specific to the carotid distribution of the endarterectomy included age, gender, type of symptom (TIA or stroke), signs of clinically evident coronary artery disease (CAD) (angina pectoris, previous myocardial infarction, congestive heart failure, previous coronary revascularization, and positive noninvasive tests for ischemia), and the presence of hypertension or diabetes mellitus. End points referable to neurologic events, vital status, and cause of death were recorded. Data from this review were transcribed into an on-line computer data entry system and edited with various range and consistency checks. These data from Olmsted County, Minn., were compared with those from NASCET.[1]

Follow-up. One hundred percent follow-up through Feb. 20, l997, for neurologic events and death was achieved through scrutiny of the entire community-wide medical record information for each patient.

Statistical methods. The Kaplan-Meier method was used to estimate the probability of survival or survival free of a neurologic event after carotid endarterectomy.[6] Survivorship curves were compared with log-rank tests.[7] Expected survival rates for the age-matched and gender-matched 1980 white Minnesota population were used for comparison.

RESULTS

Patient characteristics. Of the 297 patients undergoing elective carotid endarterectomy between l970 and 1995, TIAs or nondisabling stroke was the surgical indication in 254 patients (86%), whereas the remaining 14% had asymptomatic high-grade stenosis. This cohort of 254 symptomatic patients included 65% men and 35% women with a median age of 67 years (range, 47 to 87 years). Compared with the demographic characteristics of the NASCET participants, the Olmsted County carotid endarterectomy cohort was remarkably similar (Table I).

Specifically, mean age and gender distribution were essentially the same for the two groups with the exception that the Olmsted County cohort included 26 patients (10%) who were older than 80 years, which was an exclusion criterion for NASCET. The Olmsted County and NASCET indications for carotid operation were TIAs in the majority of patients (69% versus 67%, respectively) and nondisabling stroke in the remainder (31% versus 33%, respectively). The prevalence rates of medical comorbidity for the current population-based study and NASCET also were similar (Table I). Clinically evident CAD was common (42% versus 40%, respectively), as were hypertension (55% versus 60%, respectively) and diabetes mellitus (20% versus 17%, respectively).

Perioperative morbidity and mortality rates. The 30-day mortality rate was 1.6% for the entire 25-year period (1970 through 1995) for Olmsted

Table I. Comparison of patient characteristics of NASCET and Olmsted County, Minn., for 1970 through 1995

Characteristic	*NASCET (n = 328)*	*Olmsted County, Minn. (n = 254)*
	Percent of group	
Median age (yr)	65	67
Sex		
Male	68	65
Female	32	35
TIA at entry	67	69
Stroke at entry	33	31
Clinically evident CAD*	40	43
Hypertension	60	55
Diabetes mellitus	17	21

*Clinically evident CAD (e.g., angina pectoris, previous myocardial infarction).

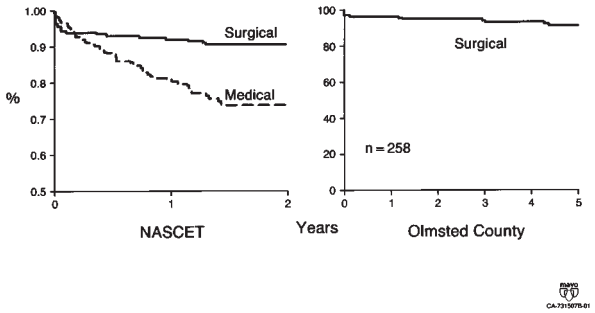

Fig. 1. Rates of survival free of ipsilateral stroke after elective carotid endarterectomy for TIAs or nondisabling stroke for NASCET[1] and Olmsted County, Minn., for 1970 through 1995. Deaths have been censored. The number of patients available for observation was 254 at onset and 82 at 5 years.

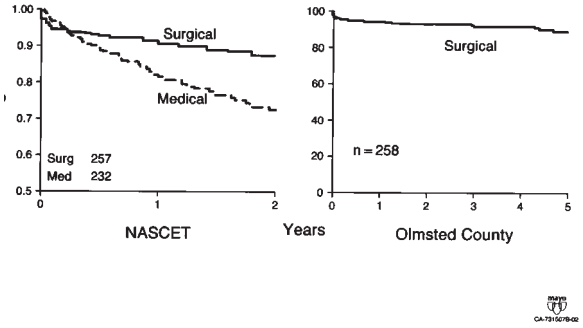

Fig. 2. Rates of survival free of any stroke for NASCET[1] and Olmsted County, Minn., for 1970 through 1995. Deaths have been censored. The number of patients for observation was 254 at onset and 80 at 5 years.

County patients compared with 0.6% for NASCET patients between l988 and 1991. Stroke in any cerebral distribution affected 3.9% of Olmsted County patients within 30 days of endarterectomy (ipsilateral stroke, 3.4%) compared with 2.1% of NASCET patients. The 30-day mortality rate for stroke was 5.1% for Olmsted County patients compared with 5.8% for NASCET patients (not significant).

In the subset of 26 patients who were older than 80 years, there were no deaths by 30 days. However, five patients had a perioperative stroke (19.2% compared with 2.2% for patients younger than 80 years, $p = 0.001$). These five strokes accounted for 50% of the perioperative strokes that occurred in the entire cohort. The indication for endarterectomy (stroke versus TIA) did not differ for patients older versus those younger than 80 years; however, nearly half of the octogenarians had their perioperative stroke after hospital discharge and in a cerebral territory remote from the carotid endarterectomy.

Long-term neurologic event outcome. Late follow-up averaged 4.3 years (range, 0 to 15.6 years) in Olmsted County compared with only 1.5 years for NASCET. The cumulative probability of ipsilateral stroke at 2 years after carotid endarterectomy in Olmsted County was 4.1% (95% confidence interval [CI], 1.6% to 6.5%) compared with 9.0% for NASCET (Fig. 1). At later follow-up in this current population-based study, survival free of ipsilateral stroke was 93% (95% CI, 90% to 97%) at 5 years and 92% (95% CI, 87% to 97%) at 10 years.

The cumulative probability of stroke in any cerebral territory was 7.0% (95% CI, 3.7% to 10.2%) at 2 years after carotid endarterectomy in Olmsted County compared with 12.6% for NASCET. At later follow-up in Olmsted County, the rate for survival free of any stroke was 90% (95% CI, 85% to 94%) at 5 years and 80% (95% CI, 72% to 90%) at 10 years (Fig. 2).

When survival to any TIA or stroke in any cerebral distribution was considered, the Kaplan-Meier survival estimates were 88% (95% CI, 84% to 92%) at 2 years, 82% (95% CI, 77% to 88%) at 5 years, and 64% (95% CI, 52% to 79%) at 10 years. NASCET has not reported survival estimates for late TIA or stroke.

Relation of risk factors to neurologic events. There was a trend toward the presence of hypertension adversely influencing the late cumulative incidence of TIAs or stroke. The cumulative incidence for hypertension versus normotension was 26% ver-

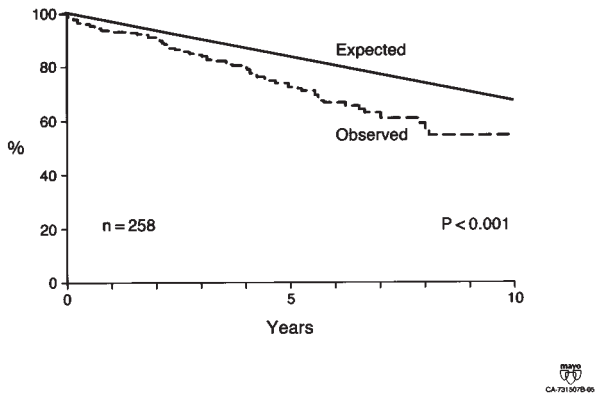

Fig. 3. Rates of survival after elective carotid endarterectomy for TIAs or nondisabling stroke for Olmsted County, Minn., for 1970 through 1995. The number of patients remaining for observation at 5 and 10 years was 88 and 18, respectively.

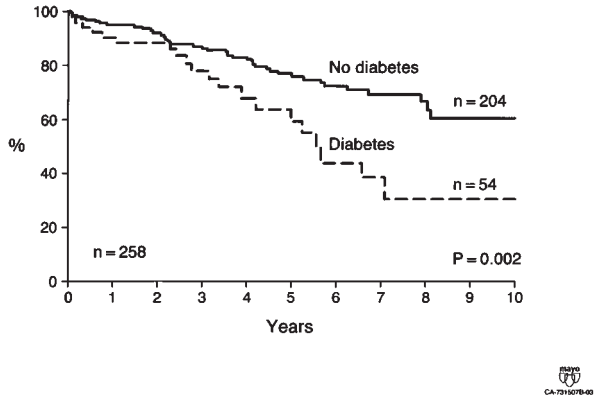

Fig. 4. Impact of diabetes mellitus on survival after elective carotid endarterectomy for Olmsted County, Minn., for 1970 through 1995. The number of patients remaining for observation at 5 and 10 years was 75 and 16, respectively, for patients without diabetes and 12 and 2, respectively, for patients with diabetes.

sus 11% (p = 0.18). Neither diabetes mellitus nor clinically evident CAD showed a significant effect on the occurrence of late neurologic events. NASCET reported that the number of medical risk factors influenced the incidence of ipsilateral stroke in medically treated patients within 2 years. However, the prognosis of surgically treated patients did not vary significantly among risk groups and was 9% at 2 years. NASCET has not published an analysis of the impact of risk factor on late neurologic events.

Long-term survival. By the end of the follow-up period, 68 of the 254 patients (27%) who underwent carotid endarterectomy in Olmsted County had died. The overall Kaplan-Meier estimate of the probability of survival was 73% (95% CI, 66% to 80%) at 5 years and 55% (95% CI, 44% to 65%) at 10 years, a significantly poorer rate than the expected survival rates of 85% and 68% (with reference to the age-and gender-adjusted 1980 Minnesota white population, p = 0.0001) (Fig. 3). Comparable estimates have not been reported by NASCET.

Table II. Total mortality rates for residents of Olmsted County, Minn., after carotid endarterectomy in symptomatic patients for 1970 through 1995

Cause of death	*No. of patients*	*(%)*
Cardiac	32	(47)
Cancer	10	(14)
Stroke	7	(10)
Pulmonary embolus	3	(4)
Ruptured abdominal aortic aneurysm	2	(3)
Other	14	(21)
Total	68	(100)

Cardiac events accounted for 32 of the 68 deaths (47%) in Olmsted County patients after carotid endarterectomy and represented the most common cause of late mortality (Table II). Stroke was recorded as the primary cause of late death in only seven patients (10%). Similarly, one third of the deaths of the surgical patients in NASCET were attributed to myocardial infarction or other ischemic heart disease, whereas stroke accounted for 13% of deaths.

Relation of risk factors to late survival. The presence of diabetes mellitus had the greatest impact of any medical comorbidity on late survival after carotid endarterectomy in Olmsted County patients (Fig. 4). Overall survival rates decreased significantly in patients with diabetes compared with patients without diabetes (p = 0.0008). The 8-year survival rate was only 27% (95% CI, 12% to 60%) for patients with diabetes compared with 67% (95% CI, 58% to 78%) for those without diabetes (p = 0.002). The presence of clinically evident CAD was associated with a trend toward a decreasing 5-year survival rate of 63% (95% CI, 52% to 75%) compared with 81% (95% CI, 74% to 89%) for no evidence of CAD (p = 0.0378) (Fig. 5). Hypertension did not demonstrate a significant impact on late survival rates.

DISCUSSION

This population-based study of elective carotid endarterectomy for symptomatic patients confirms the early beneficial results reported by NASCET and

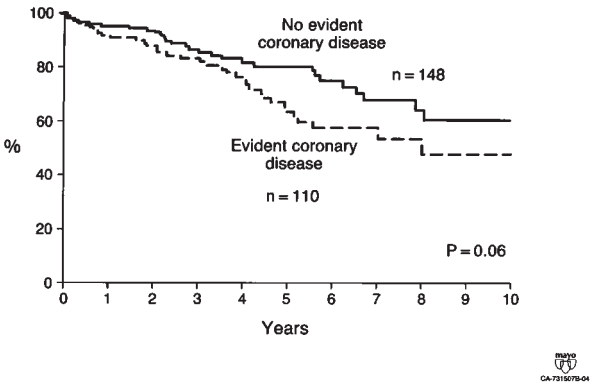

Fig. 5. Impact of clinically evident CAD on survival rates for Olmsted County, Minn., for 1970 through 1995. The number of patients remaining for observation at 5 and 10 years was 52 and 13, respectively, for those with evident CAD and 35 and 5, respectively, for those without evident CAD.

other clinical trials.[1-3] The benefits of our study occurred in a geographically defined community in which all patients undergoing carotid operation were included and a variety of vascular and neurologic surgeons performed the operation. In addition, our study exceeded the short follow-up of NASCET and added long-term confirmation that carotid endarterectomy minimized subsequent stroke. Two additional findings from our analysis deserve emphasis. More than any other risk factor, hypertension showed a trend toward increasing the late risk of TIAs or stroke after carotid operation. Second, diabetes mellitus and clinically evident CAD dramatically reduced late survival rates.

The interpretation of our comparison of Olmsted County results with those of NASCET must address the differences and similarities of the two groups. First, NASCET was a prospective, randomized trial that involved 50 medical centers. Our study was a retrospective, population-based analysis of one community and one medical center. Nevertheless, comparability was striking. The two patient cohorts were comparable in age, gender, neurologic indication for operation, and risk factors. Only a small fraction (10%) of the Olmsted County cohort was older than 80 years, an exclusion criterion for NASCET. Likewise, both studies were conducted in centers in which the combined perioperative stroke and mortality rate was established to be less than 6%.[1,8] Although the Olmsted County study covered a 25-year period compared with only a 3-year period for NASCET, we could not identify any major changes in surgical selection criteria or technique that should have biased our comparison of the two studies.

In several ways, our population-based analysis not only reinforces but also extends the risk estimates of stroke and death reported by NASCET. Until NASCET publishes its late outcomes that include the impact of risk factors on these results, the current study provides important data for predicting late clinical outcomes of carotid endarterectomy. For example, the beneficial results of carotid endarterectomy persisted for at least 10 years in Olmsted County residents. The cumulative risk of ipsilateral stroke rose only slightly from 5% at 2 years to 8% at 5 and 10% at 10 years after surgical intervention. Because all carotid operation was performed at the Mayo Clinic and the outcomes were assessed periodically by surgeons, neurologists, and interns at the clinic, it is unlikely that any early or late major neurologic events would have gone undetected. In contrast, previous population-based studies from this same community revealed an estimated risk of 35% at 5 years for ipsilateral stroke in patients with TIAs who were treated medically.[9]

Moreover, the prognostic impact of medical comorbidity on subsequent neurologic events and overall survival was confirmed in the later years of follow-up in the current population-based analysis. Control of blood pressure appears to be critical in alleviating stroke risk after carotid endarterectomy, a finding corroborated with other studies from this same community in which the role was examined of hypertension in accelerating the risk of stroke in medically treated patients.[10-12] The size of our current study cohort and the small number of late neurologic events may have limited our ability to determine other definitive relations between risk factors and stroke. However, in a larger study of 1804 residents of Rochester, Minn., between l960 and 1973, the individual relative risks for eventual stroke were 4.0 for hypertension, 2.2 for CAD, and 1.7 for diabetes mellitus.[10]

Two risk factors had notable impacts on late survival after carotid operation. Within 3 years, the presence of diabetes mellitus had a profoundly negative impact on survival rates, whereas clinically evident CAD showed its most important influence on worsening survival rates after 4 years. Our previously reported analysis of l77 carotid endarterectomies between l970 and 1987 emphasized the importance of identifying CAD and maximizing its long-term management.[13]

The results of both our population-based study and NASCET must be interpreted with several cau-

tions. First, these recommendations apply to surgeons whose perioperative stroke and death rates are less than 5% to 6%. The NASCET collaborators emphasized that all benefits of carotid endarterectomy may be lost if the rate of major complications approaches 10%.[1] Also, these data do not address whether carotid operation is likely to benefit patients with (1) more disabling strokes, (2) progressing strokes in evolution, (3) chronic organ failure (e.g., dialysis-dependent chronic renal failure or chronic congestive heart failure), (4) atrial fibrillation or other sources of cerebral emboli plus high-grade carotid stenosis, or (5) diffuse cerebrovascular disease (e.g., multiple extracranial brachiocephalic stenoses or intracranial small vessel disease).

In addition, previous randomized trials have not addressed the increasing issue of whether carotid endarterectomy benefits the symptomatic patient who is older than 80 years. In a recent Mayo Clinic study of 749 carotid endarterectomies in symptomatic patients older than 70 years, 56 patients (7%) were older than 80 years.[14] This previous referral-based study included our larger regional practice, which attracts patients who are sufficiently healthy to make the trip to Rochester. Sicker or more debilitated patients may not be referred or may choose not to make the trip. Thus these selected referral patients are generally better operative risks than those of our community practice, which includes all patients regardless of medical comorbidity.

In our previous referral-based study, the combined perioperative combined stroke and mortality rate was 5.4% for patients older than 80 years.[14] These referral practice results are considerably better than the 19% perioperative stroke rate observed in the current population-based study. Nearly half of the postoperative strokes in community octogenarians occurred after hospital discharge and often in cerebral distributions unrelated to the carotid endarterectomy. Therefore one must carefully select symptomatic octogenarians for carotid endarterectomy. The use of antiplatelet agents or warfarin anticoagulation may be preferable to carotid endarterectomy for some symptomatic octogenarians with serious medical comorbidity. Currently, it is too early to determine the appropriate role of carotid stent angioplasty in such patients.

Finally, population-based studies provide a relatively unbiased method to estimate the long-term results of multicenter, randomized clinical trials, provided the patient characteristics and management protocols for the two groups are comparable. Limited by constraints of accrual time and funding, randomized trials often have remarkably short follow-up periods (i.e., an average of 2 to 3 years). In contrast, population-based data usually encompass multiple years and sometimes explore decades of late outcome. Consequently, the present population-based study not only confirms the early benefits of carotid endarterectomy reported by NASCET but also implies that the results can be replicated in community patients treated by expert surgeons and are remarkably durable.

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DISCUSSION

Dr. Donald Silver (Columbia, Mo.). I thoroughly enjoyed this presentation by Dr. Hallett. In 1991, the North American Symptomatic Carotid Endarterectomy Trial (NASCET) reported results for a randomized trial during which 659 patients who had hemispheric or retinal ischemic attacks or nondisabling stroke within the previous 120 days and who had a 70% to 99% stenosis were treated either medically or by carotid endarterectomy. The results were so supportive of the benefits of the role of carotid endarterectomy that the study was terminated early. The study reported a 26% ipsilateral stroke rate in the medical patients after 2 years and a 9% ipsilateral stroke rate in the surgical patients. Fatal ipsilateral stroke rates were 13% and 2.5%, respectively. The NASCET report firmly established the beneficial role of carotid endarterectomy for a symptomatic patient with carotid stenosis.

Dr. Hallett and his colleagues at the Mayo Clinic have presented review of all the patients in Olmsted County, Minn. who had a carotid endarterectomy for TIA or disabling stroke in the 25-year period between 1970 and 1995. All the carotid endarterectomies were performed at the Mayo Clinic; 297 patients had 312 carotid endarterectomies, and 85% of the patients had transient ischemic attacks and nondisabling strokes. Survival without ipsilateral stroke was 95% in 2 years, 92% in 5 years, and 90% in 10 years. The results (91% at 2 years) were similar to the results of the NASCET study. The 30-day operative mortality rate was 1.6% for the Mayo Clinic group. Stroke was the cause of death in eight patients in the Mayo Clinic group as compared with 13% for the NASCET patients.

Dr. Hallett and his colleagues have noted that hypertension is a major risk factor that contributes to the increased risk of transient ischemic attacks or stroke after carotid endarterectomy. Diabetes and ischemic heart disease reduced the survival rate of their patients. This study has been a long-term study of patients from a single community who had a carotid endarterectomy for transient ischemic attacks or disabling stroke.

I have some questions for Dr. Hallett that concern this study. First, the NASCET selected centers with skilled surgeons who had a rate of less than 6% for stroke and death within 20 days of an operation. Dr. Hallett noted that the perioperative stroke immortality rate was less than 6% at the Mayo Clinic. One wonders whether these rates were uniform among all the surgeons in the Mayo Clinic.

Second, the percent stenoses of carotid arteries was carefully documented by neuroradiologists in the NASCET study. In the manuscript, the percent of carotid stenoses in patients in Olmsted County was not discussed. Did some of your patients have ulcers, or did some patients have less than 50% stenoses?

Third, did all of your patients receive antiplatelet treatment as the patients did in the NASCET study? If so, what form of platelet inhibition do you prefer?

Fourth, the NASCET study excluded patients who did not have angiographic visualization of the carotid arteries. Did you perform carotid endarterectomy without angiograms?

Fifth, please comment upon the type of anesthesia you use. Our current choice is regional cervical block.

Your report not only confirms the recommendation of NASCET for carotid endarterectomy for high-grade symptomatic carotid stenosis but also demonstrates that the beneficial results exist for at least 10 years. We thank you for sharing these data from the Mayo Clinic with us.

Dr. John W. Hallett. Thank you, Dr. Silver. Anticoagulation or antiplatelet therapy in the lesions included in this study ranged from one baby aspirin a day to two regular aspirin per day. Angiography was used in all of the patients in this period of time. Although we use ultrasound scan alone for asymptomatic patients in general, we have used some type of arteriography, either intravenous, standard intraarterial, or magnetic resonance, for the evaluation of these symptomatic patients before operation. General anesthesia with electroencephalography monitoring has been the standard at the clinic for over 25 years. All of the patients in this study had that type of anesthesia.